K110768

APR 20 2011

510(k) Summary

Schick Computed Oral Radiology System

Common/Classification Name: Solid State X-ray Imager
21CFR892.1650

Schick Technologies
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Long Island City, NY 11101
718-937-5765
718-937-5962 (fax)
Contact: Scott Doyle sdoyle@schicktech.com

A. Legally Marketed Predicate Devices

The computer oral radiology system was most recently cleared under K072134; November 2, 2007. The device and its predicates are small digital imaging receptors that may be used in place of dental x-ray film. The images are displayed on a computer workstation.

B. Modification Description

Modifications to the device from its immediate predicate (K072134) are related to making it a wireless (WiFi) device vice a USB connected device.
The modified device uses wireless IEEE 802.11 b/g protocol for image data transfer and control signal transfer to and from the Power and Transceiver (PAT) and the host computer. A rechargeable battery power source is also included in the PAT.
A Counter Top Dock (CTD) has been added to this system. The CTD is a support device that provides charging power to the PAT and is used to provide a temporary wired connection, via USB, from the host computer to the PAT to allow initial configuration to the host wireless network.
The modification does not alter the fundamental technology or the intended use.

C. Intended Use

The operational environment remains unchanged from the predicate.
There are no changes to the indications for use from the predicate devices.

D. Substantial Equivalence Summary

The modified system has had risks evaluated and mitigated as necessary. Testing and design validation have been used to verify risk mitigation. The principal risk is imaging system failure causing a retake which may include additional X-ray exposure.

E. Conclusion

Schick Technologies has concluded the modified system is substantially equivalent to its predicates. Risk analysis, testing and validation studies support this conclusion

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Scott Doyle
Project Manager
Schick Technologies, Inc.
30-30 47th Avenue
LONG ISLAND CITY NY 11101

APR 20 2011

Re: K110768
Trade/Device Name: Computed Oral Radiology System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: March 17, 2011
Received: March 22, 2011

Dear Mr. Doyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110768

Device Name: Computed Oral Radiology System

Indications for Use:

The Computed Oral Radiology System is indicated for patients undergoing an intra-oral dental x-ray examination. It produces instant, digital, intra-oral images of a patient's mouth while reducing the necessary x-ray dosage.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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